

Summary of changes for Pfizer-BioNTech Dose Order Configuration, Ancillary Kits, and Storage and Handling

The US Food and Drug Administration (FDA) has amended the Pfizer-BioNTech COVID-19 Emergency Use Authorization (EUA) to include the following:

1. A new Pfizer 450-dose order configuration
2. Changes in storage temperatures for undiluted vials

The new EUA allows for a new 450 dose configuration. Both the 1170 dose and 450 dose product configurations will be in circulation and reflected in your weekly allocations and ordering caps beginning on May 25th and 27th. A new NDC has been issued for the smaller Pfizer configuration.

Pfizer 450 **NEW**	NDC 59267-1000-03	75 Multidose vials (3 trays of 25 vials each)
Pfizer 1170	NDC 59267-1000-02	195 Multidose vials

Key Facts about the 450-dose pack

- The new 450-dose pack includes 3 trays of 25 vials each.
- Vials will be shipped in the same container as the 1,170-dose orders and will include the same Controlant temperature monitor.
- The newly extended refrigerator storage temperatures (see below) should decrease the need for dry ice.
 - Therefore, Pfizer asks that the shippers and Controlant monitors be returned within 10 days.
 - **There will be no dry ice replenishment for the 450-dose pack.**
- The minimum order size is 450 doses.
 - For orders over 450, we ask awardees to consider ordering the 1,170 dose package.
 - Roughly 35% of the Pfizer allocations will consist of the 450-dose pack.

New Ancillary Kits

- New ancillary kits have been created to support the 450-dose minimum order size.
- When placing orders, awardees should select an order intention of Adult or Pediatric for their Pfizer 450 order. This information will determine which ancillary kit is shipped with the vaccine. This is a change from COVID-19 vaccine ordering since the program first started, for which all vaccines had to be ordered with an Adult order intention.
- The adult ancillary kits contain the same ratio of 1" to 1.5" needles as the 1,170 kit.
- The pediatric ancillary kit contains only 1" needles.
- All other supplies in the kit remain the same.

The table below provides information on the order and delivery dates of Pfizer 450 packs. Week 1 orders reflect delivery days that are irregular due to the Memorial Day holiday. Note: There are no deliveries on Memorial Day, Monday, May 31st.

Week 1	
Order Day	Delivery Day
Friday, Saturday, Sunday (May 28–30)	Tuesday–Wednesday (June 1-2)
Monday, Tuesday, Wednesday (May 31–June 2)	Wednesday–Friday (June 2-4)
Following Weeks	
Order Day	Delivery Day
Thursday, Friday, Saturday, Sunday	Monday–Wednesday
Monday, Tuesday, Wednesday	Wednesday–Friday

Storage and Handling

FDA has amended the Pfizer EUA to allow undiluted, thawed Pfizer COVID-19 Vaccine vials to be stored in the refrigerator at 2°C - 8°C for up to 1 month.

- The Pfizer COVID-19 vaccine vials must remain undiluted to remain at 2°C - 8°C for 1 month.
- **The up to 1-month 2°- 8° C storage duration must be within the labeled expiration date (i.e., not cumulative).**

Step down storage & handling for Pfizer COVID vaccines is now as follows:

- **All Pfizer configurations are shipped ultra-cold**
- Ultra-Cold (-70)
 - May be stored in ULT freezer until the expiration date, or temporary in the shipper with regular dry ice replenishment.
- Frozen (-20)
 - Pfizer COVID-19 vaccine vials may remain frozen at -20°C for up to 2 weeks. (unchanged)
- Refrigerated (2-8)
 - Pfizer COVID-19 undiluted vaccine vials may remain at 2°C - 8°C for 1 month.
- **Total storage time for Pfizer in freezer and refrigerator should not exceed 45 days.**